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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/483,434	01/14/00	MILLER J	14014.0360

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EXAMINER	
LEFFERS JR,G	
ART UNIT	PAPER NUMBER
1636	11

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/483,434	Applicant(s) Miller, et al.
	Examiner Gerald G. Leffers Jr.	Group Art Unit 1636

☒ Responsive to communication(s) filed on *Feb 9, 2001*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-5 and 7-18* is/are pending in the application.

Of the above, claim(s) *4, 5, 8, and 11-14* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 9, 10, and 15-17* is/are rejected.

☒ Claim(s) *7 and 18* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Receipt is acknowledged of applicants' amendment, filed 2/9/01 as Paper No. 10, in which applicants amended claims 1 and 7, canceled claim 6 and added new claims 15-18. Claims 1-5, 7-18 are pending, with claims 4-5, 8 and 11-14 being withdrawn from consideration as being drawn towards nonelected inventions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Al-Hakim et al (A) (see the entire patent). **This rejection is maintained for reasons of record in Paper No. 9, mailed 11/07/00 and repeated below.**

Al-Hakim et al teach the construction and use of non-radioactive nucleic acid probes (Abstract). These probes feature an adduct of a basic macromolecule and biotin in which the macromolecule can be polyethylenimine (PEI) and in which the adduct can be cross-linked to a nucleic acid to form a non-radioactive nucleic acid hybridization probe (column 1, line 67 to column 2, line 68). The patent teaches that hybridization of the probe to the target nucleic acid

sequence can be detected by an avidin-enzyme label complex which binds tightly to the biotinylated nucleic acid-PEI probe (column 3, lines 0-15).

Response to Arguments

Applicant's arguments filed 2/9/01 have been fully considered but they are not persuasive.

Applicants' response argues that Al-Hakim et al does not disclose a complex comprising avidin and that Al-Hakim et al specifically do not disclose a PEI-avidin adduct. This argument is not persuasive because Al-Hakim et al do disclose a complex comprising a biotinylated nucleic acid-PEI/avidin-enzyme composition. The patent teaches that hybridization of the biotinylated nucleic acid probe to the target nucleic acid sequence can be detected by an avidin-enzyme label complex which binds tightly to the biotinylated nucleic acid-PEI probe (column 3, lines 0-15). The argument that Al-Hakim does not disclose a PEI-avidin adduct is irrelevant as this limitation is not present in the open claim language recited in the rejected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Each of the rejected claims is drawn towards a method for delivery of a biologically active biomolecule to the surface of a cell wherein a first molecule is covalently attached to the surface of the cell to form a receptor, a biologically active molecule is complexed with a ligand for the first, covalently-attached molecule, and contacting the biologically active molecule-ligand complex with the cell surface. Claims 1-3 comprise the further limitation of delivery of the biologically active molecule to the surface of the cell. The claims literally encompass the attachment of any molecule to the surface of a cell of any type wherein the first molecule will specifically bind a ligand such that a biologically active molecule complexed with the ligand can be delivered specifically to the cell surface. The claims also encompass any active biomolecule, including such diverse biomolecules as peptides, nucleic acids, lipids and carbohydrates complexed with a carrier molecule to which the ligand is complexed. The claims are thus very broad genus claims encompassing any possible "receptor/ligand" binding pair as well as any biologically active molecule, regardless of chemical structure.

The only description provided in the specification with regard to a "receptor"/ligand binding pair is where biotin has been covalently attached to the surface of a target cell to provide a synthetic receptor to which an avidin (or streptavidin)/biologically active molecule complex can bind. The description of such ligand/biologically active molecule complexes is further limited in the specification to complexes wherein the ligand (i.e. avidin or streptavidin) is

complexed with polyethylenamine (PEI) as well as with the biologically active molecule. The only biologically active molecules for which their is a significant description as part of the ligand/active molecule complex are nucleic acids and polypeptides. There is no significant description or relevant example in the specification of any first molecule covalently attached to the surface of a target cell other than biotin. There is no significant description or relevant example in the specification for a ligand/biologically active molecule complex other than complexes comprising avidin (or streptavidin) complexed with PEI, and further complexed with either a polypeptide or a nucleic acid.

Given the very broad scope of the rejected claims regarding the first molecule attached covalently to the surface of a target cell as well as the broad scope regarding the corresponding ligand/active molecule complex, the lack of description or relevant example in the specification of other such first molecule/ligand/active molecule combinations, and the different chemical/structural requirements for different "receptor" molecule/ligand/active molecule complexes, one of skill in the art would not be able to envision a representative number of embodiments wherein a different first molecule is attached to the surface of the target cell and a corresponding ligand is complexed with a desired active molecule. Moreover, even for the smaller genus wherein the first "receptor" molecule/ligand pair is biotin/avidin (or streptavidin), one of skill in the art would not be able to envision a representative number of embodiments wherein the active molecule is other than a nucleic acid or peptide. Therefore, one of skill in the art would reasonably conclude that applicants were not in possession of the claimed genus.

Conclusion

Claims 1-3, 9-10, 15-17 are rejected. Claims 7 and 18 are objected to as being dependent upon a rejected claim. Claims 7 and 18 would be allowable if rewritten as independent claims incorporating each of the limitations of the claim from which they currently depend.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GLL

G. Leffers, Jr.

Patent Examiner

Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER

April 23, 2001